Scivolutions, Inc
Art Ward
Medical Device Consultant
962 Allegro Ln.
Apollo Beach, Florida 33572

November 15, 2021

Re: K020318
Trade/Device Name: Scivolutions Various Antibacterial Bandages
Regulatory Class: Unclassified
Product Code: FRO

Dear Art Ward:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 3, 2003. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code FRO.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, Ph.D., OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 3 2003

SciVolutions, Inc.
Alan Nash
268 Tosca Drive
Stoughton, Massachusetts 02072

Re: K020318
Trade/Device Name: SciVolutions Antibacterial Bandages
Regulatory Class: Unclassified
Product Code: MXE: Medical Adhesive Tape and Bandage with Disinfectant
Dated: December 19, 2002
Received: December 24, 2002

Dear Mr. Nash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020318

510(k) Number (if known): K020318

Device Name: SciVolutions, Inc. Antibacterial Adhesive Bandages

Indications For Use:

Antibacterial Adhesive Bandages are to be applied to the skin for topical application. The bandages help provide an antibacterial barrier for minor cuts and scrapes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Miriam C. Provost

Restorative
Devices

K020318

FEB 0 3 2003

510(K) SUMMARY
K020318
(as required by 807.92(c))

Submitter of 510(k):

SciVolutions, Inc.
268 Tosca Dr.
Stoughton, MA 02072

Phone: 781-344-3211
Fax: 781-344-9203

Contact Person: Alan Nash

Date of Summary: November 4, 2002

Trade Name: SciVolutions Antibacterial Bandages

Classification Name: Tape and bandage, Adhesive (with disinfectant)

Predicate Device:

K992817 William Feinstein and Associates, Inc. Anti-Bacterial Adhesive Bandage

Intended Use:

Antibacterial Adhesive Bandages are to be applied to the skin for topical application. The bandages help provide an antibacterial barrier for minor cuts and scrapes.

Product Description:

Antibacterial adhesive bandages are similar to many pre-amendment and already cleared products with benzalkonium chloride. They are provided in various sizes in a box for over the counter purchase. The benzalkonium chloride concentration is 1%.